DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2005

Mr. Lieven De Wandel
Official Correspondent
Barco View
Medical Imaging Systems
35 President Kennedypark
Kortrijk 8500
BELGIUM

Re: K051201
Trade/Device Name: E1 Medical Flat Panel Display System and MFGD 1218 Medical Flat Panel Display
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 29,2005
Received: May 11,2005

Dear Mr. De Wandel:

This letter corrects our substantially equivalent letter of May 26, 2005 regarding the E1 Medical Flat Panel Display System and MFGD 1218 Medical Flat Panel Display. The MFGD 1218 Medical Flat Panel Display was inadvertently left off the original letter. This letter applies to both devices listed above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K051201

Device Name: E1 Medical Flat Panel Display System

Indications for Use:

The E1 Medical Flat Panel Display System is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use __XX___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061201

Indications for Use

510(k) Number (if known): K051201

Device Name: **MFGD** 1218 Medical Flat Panel Display

Indications for Use:

The MFGD 1218 Medical Flat Panel Display is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051201

MAY 26 2005

K051201

510(k) Summary

In accordance with 21 CFR 807.92

1. Date of preparation

April 29, 2005 – Modified May 23, 2005

2. Company information

BarcoView
35 President Kennedypark
B-8500 Kortrijk, Belgium
Tel. +32-(0)56-233-211
Fax +32-(0)56-233-457

3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: E1 Medical Flat Panel Display System
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: Nio 2MP Medical Flat Panel Display System
- 510(k) number: K042660
- Manufacturer: Barco NV

6. Device description

E1 is a display system for medical viewing. It consists of 3 components:
MFGD 1218 is an 18" grayscale LCD display. BarcoMed Nio is a fast high-resolution display controller board that plugs into a PACS workstation computer. NioWatch is user-friendly software that allows to optimize the display for DICOM-compliant viewing.

7. Intended use

The E1 Medical Flat Panel Display System is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

8. Summary of technological characteristics

The device consists of three components:

1. One 1-megapixel flat panel display (MFGD 1218)
2. One 10-bit display controller (BarcoMed Nio board)
3. NioWatch software

Barco n.v.
Pr. Kennedypark 35
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Tel.: +32 56 233 211 - Fax: +32 56 233 457

The flat panel display has a resolution of 1280 x 1024 pixels. It can be used in landscape mode only.
The display controller board is an ultra-high speed board with an 8-bit in, 10-bit out lookup table, providing 256 simultaneous shades of gray.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the display from the E1 system has a smaller native resolution and does not contain an internal backlight sensor.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

9. Conclusion:
The Barco E1 Medical Flat Panel Display System is substantially equivalent to the predicate device, Nio 2MP Medical Flat Panel Display System.
The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.
Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco E1 Medical Flat Panel Display System contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

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510(k) Summary

In accordance with 21 CFR 807.92

1. Date of preparation

April 29, 2005 – Modified May 23, 2005

2. Company information

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3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: MFGD 1218 Medical Flat Panel Display
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: Nio 2MP Medical Flat Panel Display System
- 510(k) number: K042660
- Manufacturer: Barco NV

6. Device description

MFGD 1218 is an 18" grayscale LCD display for medical viewing. It is combined with NioWatch, a user-friendly software that allows to optimize the display for DICOM-compliant viewing.

7. Intended use

The MFGD 1218 Medical Flat Panel Display is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

8. Summary of technological characteristics

The flat panel display has a resolution of 1280 x 1024 pixels. It can be used in landscape mode only.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display information.

Compared to the display in the predicate device, the MFGD 1218 display has a smaller native resolution and does not contain an internal backlight sensor.

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The device does not come into contact with the patient. It does not control any life sustaining devices either.

9. Conclusion:

The Barco MFGD 1218 Medical Flat Panel Display is substantially equivalent to the predicate device, Nio 2MP Medical Flat Panel Display System.
The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.
Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MFGD 1218 Medical Flat Panel Display contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

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